

## Food and Drug Administration, HHS

## § 17.34

(HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, shall include an original and two copies.

(2) The first page of every pleading and paper filed in the proceeding shall contain a caption setting forth the title of the action, the case number assigned by the Office of the Chief Counsel, and designation of the pleading or paper (e.g., “motion to quash subpoena”).

(3) Every pleading shall be signed by, and shall contain the address and telephone number of, the party or the person on whose behalf the pleading was filed, or his or her counsel.

(4) Pleadings or papers are considered filed when they are received by the Division of Dockets Management.

(b) *Service.* A party filing a document with the Division of Dockets Management under this part shall, no later than the time of filing, serve a copy of such document on every other party. Service upon any party of any document, other than service of a complaint, shall be made by delivering a copy personally or by placing a copy of the document in the United States mail or express delivery service, postage prepaid and addressed, to the party’s last known address. When a party is represented by counsel, service shall be made on such counsel in lieu of the actual party.

(c) *Proof of service.* A certificate of the individual serving the document by personal delivery or by mail, setting forth the time and manner of service, shall be proof of service.

### § 17.32 Motions.

(a) Any application to the presiding officer for an order or ruling shall be by motion. Motions shall state the relief sought, the authority relied upon, and the facts alleged, and shall be filed with the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, delivered to the presiding officer, and served on all other parties.

(b) Except for motions made during a prehearing conference or at the hearing, all motions shall be in writing. The presiding officer may require that oral motions be reduced to writing.

(c) Within 15 days after a written motion is served, or such other time as may be fixed by the presiding officer, any party may file a response to such motion.

(d) The presiding officer may not grant a written motion before the time for filing responses thereto has expired, except upon consent of the parties or following a hearing on the motion, but may overrule or deny such motion without awaiting a response.

### § 17.33 The hearing and burden of proof.

(a) The presiding officer shall conduct a hearing on the record to determine whether the respondent is liable for a civil money penalty and, if so, the appropriate amount of any such civil money penalty considering any aggravating or mitigating factors.

(b) In order to prevail, the Center must prove respondent’s liability and the appropriateness of the penalty under the applicable statute by a preponderance of the evidence.

(c) The respondent must prove any affirmative defenses and any mitigating factors by a preponderance of the evidence.

(d) The hearing shall be open to the public unless otherwise ordered by the presiding officer, who may order closure only to protect trade secrets or confidential commercial information, as defined in §20.61 of this chapter, information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, or other information that would be withheld from public disclosure under part 20 of this chapter.

### § 17.34 Determining the amount of penalties and assessments.

(a) When determining an appropriate amount of civil money penalties and assessments, the presiding officer and the Commissioner of Food and Drugs or entity designated by the Commissioner to decide the appeal (currently the DAB) shall evaluate any circumstances that mitigate or aggravate the violation and shall articulate in their opinions the reasons that support the penalties and assessments imposed.

(b) The presiding officer and the entity deciding the appeal shall refer to the